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HL

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/875,888	08/06/97	BRODIN	ABA300/13003

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EXAMINER

COOK, R

ART UNIT	PAPER NUMBER
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1614

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DATE MAILED: 06/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/575888

Applicant(s)

Brodin et al

Examiner

Cocke

Group Art Unit

1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 6/14/99
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-12, 17-18 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-12, 17-18 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 15
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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Claims 1-12, 17-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the concentrations of surfactant disclosed in the examples, does not reasonably provide enablement for the invention as claimed. The invention as claimed is not enabled.

EP 455 396, U.S. 5,635,540 and 4,780,320 disclose that compositions comprising one or more local anaesthetics in oil form, one or more surfactants having thermoreversible gelling properties and water form single phase gel or cream compositions. Applicants argument that the compositions of the invention tend to use an amount of surfactant that is either outside the range of the prior art or at the extreme lower end is not persuasive. Page 5 of the specification discloses that the total amount of surfactant(s) is preferably present in an amount of up to 50% by weight.

Additionally, the specification discloses only an oil-in-water emulsion or microemulsion and it is not seen that a water-in-oil emulsion or microemulsion is contemplated.

Claims 1-12 and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, (I) the term "oil form" is unclear, since on page 6 the term used is "oil phase."

In (ii) the intent of the recitation "one or more surfactants ... wherein at least one surfactant has thermoreversible gelling properties" is unclear when there is only one surfactant.

Claim 17 is confusing. Since the word "administering" is generally understood to mean oral or parenteral route and the specification does not define it. Amending the recitation to claim

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that the composition is applied to the periodontal pocket of the patient would overcome this rejection.

owl
ok
Claim 18 is not clear.

The recitation in parentheses in (I) is confusing, since it is not clear how to prepare the composition if only one surfactant is used. Additionally, it is not clear that (I) and (iii) are alternative steps and (iv) does not occur if alternative (I) is used.

The pH and weight are not recited and it is not clear what they are intended to be.

“Slowly” is a relative term which is not defined in the specification.

The specification does not disclose what a “suitable” acid or base would be.

In view of the amendments to the claims the earlier rejections under 35 U.S.C. 112, paragraph two are withdrawn.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by FR 2 704 429 and Nyqvist-Mayer et al.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nyqvist-Mayer et al or Fr 2 704 429.

The reference discloses The pharmaceutical emulsion of claim 1. The remaining claims differ over the references in requiring specific limitations, method of preparation and method of use. However, it would be obvious to one of ordinary skill in the art to use the specific limitation, method of preparation and method of use because once the composition is known it would be within the skill of the artisan to optimize the composition with the particulars. Additionally, it would be obvious to use a topical anesthetic composition to anthesize a periodontal cavity, since the disclosed topical anesthetics are well known in the art for dental use. Furthermore, no unobviousness is seen in the method of preparation, since each of the recited steps is conventional in the art.

Any inquiry concerning this communication should be directed to Examiner Cook at telephone number (703) 308-1235.


REBECCA COOK
PRIMARY EXAMINER
GROUP 1200

June 23, 1999